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ATTORNEY DOCKET NO. APPLICATION NO. FILING DATE FIRST NAMED INVENTOR G AR138-X HAMILTON 12/03/98 09/204,238 **EXAMINER** HM12/0727 CHANG, C NATH AND ASSOCIATES 1030 FIFTEENTH STREET N W ART UNIT PAPER NUMBER SIXTH FLOOR 1625 WASHINGTON DC 20005

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

07/27/00

PTO-90C (Rev. 2/95) U.S. G.P.O. 1999 460-693 1- File Copy

Application No. 09/204,238

Applicant(s)

Hamilton et al.

Examiner

Office Action Summary

Celia Chang

Group Art Unit 1625

| Responsive to communication(s) filed on May 8, 2000 | |
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| This action is FINAL. | |
| Since this application is in condition for allowance except for for in accordance with the practice under Ex parte Quayle, 1935 C. | rmal matters, prosecution as to the merits is closed .D. 11; 453 O.G. 213. |
| A shortened statutory period for response to this action is set to exs longer, from the mailing date of this communication. Failure to respond to become abandoned. (35 U.S.C. § 133). Extensions 37 CFR 1.136(a). | espond within the period for response will cause the |
| Disposition of Claims | |
| X Claim(s) 1-11, 14-25 | is/are pending in the application. |
| Of the above, claim(s) | is/are withdrawn from consideration. |
| Claim(s) | |
| ☑ Claim(s) 1-11 and 14-25 | |
| ☐ Claim(s) - * | |
| ☐ Claims | |
| Application Papers | |
| ☐ See the attached Notice of Draftsperson's Patent Drawing Re | eview, PTO-948. |
| ☐ The drawing(s) filed on is/are objected | to by the Examiner. |
| ☐ The proposed drawing correction, filed on | is _approved _disapproved. |
| \square The specification is objected to by the Examiner. | |
| ☐ The oath or declaration is objected to by the Examiner. | |
| Priority under 35 U.S.C. § 119 | |
| Acknowledgement is made of a claim for foreign priority und | ler 35 U.S.C. § 119(a)-(d). |
| ☐ All ☐ Some* ☐ None of the CERTIFIED copies of the | e priority documents have been |
| ☐ received. | |
| ☐ received in Application No. (Series Code/Serial Numbe | r) |
| \square received in this national stage application from the Inte | ernational Bureau (PCT Rule 17.2(a)). |
| *Certified copies not received: | |
| ☐ Acknowledgement is made of a claim for domestic priority u | nder 35 U.S.C. § 119(e). |
| Attachment(s) | • |
| Notice of References Cited, PTO-892 | |
| ☐ Information Disclosure Statement(s), PTO-1449, Paper No(s) | · |
| ☐ Interview Summary, PTO-413 | |
| ☐ Notice of Draftsperson's Patent Drawing Review, PTO-948 | |
| □ Notice of Informal Patent Application, PTO-152 | |
| | |
| SEE OFFICE ACTION ON THE | FOLLOWING PAGES |

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DETAILED ACTION

- 1. Amendment and response filed in paper No. 17, dated May 8, 2000 have been entered and considered carefully. Claims 12-13, 26-71 have been canceled. Claims 1-11, 14-25 are pending.
- 2. The rejection of claims 1-11 under 35 USC 112 second paragraph is maintained with the amended claims and rejected under 35 USC 112 first paragraph under the NEW MATTER for the following reason.

Applicants attempt to employ the term "alkylenyl" for moiety "D" is erroneous and constitute NEW MATTER. Please note that the term "alkylenyl' lack antecedent basis in the specification. In addition, the hack's chemical dictionary is provided that a linker with two open valence is call 'alkylene' and no term "alkylenyl" can be found in the dictionary.

Removal of all new matter is required. In re Ressemussen 211USPQ 325.

The arguments that the carboxylic acid isostere has been defined in the specification is not the basis for determining the scope of the claims. If the R2 moieties, irrespective of its function are those disclosed on page 16, then, such limitation can not be read into the claims but must be incorporated by the claims. If applicant's arguments is referring to that the functionality of carboxylic acid moiety and hydroxy or hydroxy alkyl are the same and are isosteric in nature, then, evidence is lacking that such functional replacement is recognized in the art.

3. The rejection of claims 1-4 under 35 USC 102(b) over Henery-Logan, Andrew or Dunkerton is maintained for reasons of record.

Applicants argued that the prior art of Henry-Logan, Andrews of Dunkerton references disclosed 2-ester substituted heterocyclic compounds which are provisosed out.

Please note that the prior art compounds are D is bond, R2 is an carboxylic acid isostere i.e. carboxylic acid ester. Please note that the meaning of isosterism functionality being inclusive

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of the carboxylic acid ester is a well known fact as evidence by Fludzinski et al, Derwent 87-46657. For such well known facts, exhausted listing for such information will not be provided. The PTO should interprete the scope of the claims during examination to the "broadest" interpretation and not limited to those items exemplified by the specification. In re Heck 216 USPQ 1038; Ex parte Isaksen 23 USPQ2d 1001. Therefore, the interpretation of isostere as being drawn to those compounds recited in the prior art is correct and anticipation is found.

4. The rejection of claims 1-5 under 35 USC 103(a) over Henery-Logan, Andrew of Dunkerton is maintained for reason of record.

It has been explained clearly that anticipation was found for the species delineated by the prior art. Any compounds encompassed by the claims constitute an one methyl addition or one methylene insertion would be an obvious variation of the prior art compound. The fact that the instant claims are drawn to a different utility is immaterial because the prima facie obvious compounds are expected to have similar utility as the prior art. Please note that claims 1-5 are compound per se claims. Arguments regarding utility must be based on a meaningful showing of an expected difference in properties of applicants' compounds versus the compounds of the prior art. In re hock 166 USPQ 406; in re Payne 203 USPQ 247.

5. The rejection of claims 1-11, 14-25 under the judicially created doctrine of obviousness type double patenting over claims 1-12 of US 5,801,187 is maintained for reasons of record.

The gist of applicants' argument is that an ester is not considered a carboxylic acid isostere. This is not persuasive. Please note that not only the disclosed isostere such as tetrazolyl, triazolyl, oxadiasolyl such as explicitly described in claim 3 page 67 are well known isosteric replacements of carboxylic acid as well as carboxylic acid esters (see CA 122:314,423, CA 120:54750). It is further pointed out that the amended claims are drawn to D is methylene, R2 is OR3 compounds, i.e. CH2OR3 wherein R3 is C1-6 alkyl. This compound is an bioisosteric

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replacement of the esters wherein the carbonyl is replace with a isostere moiety methylene (see CA 67:10051). Or, please note that D is bond R3 is COOR4 and R4 is C1-9 alkyl, it <u>is</u> and ester and not proviso can be found that such ester is excluded.

6. Applicant's amendment necessitated the recitation of the new references presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Celia Chang whose telephone number is (703) 308-4702.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

CCC/Chang

July 26, 2000

CEILA CHANG PRIMARY EXAMINER GROUP 1200-17